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PATENT  
Attorney Docket No.: 022101 001910

Mail Stop Patent Application  
Commissioner for Patents  
PO Box 1450  
Alexandria VA 22313-1450

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Gagner, et al.

Application No.: Not Assigned

Filed: March 25, 2004

For: Method for Determining the  
Efficiency of Nucleic Acid Amplifications

Examiner: Not Assigned

Art Unit: Not Assigned

INFORMATION DISCLOSURE  
STATEMENT UNDER 37 CFR §1.97 and  
§1.98

Mail Stop: Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The references cited on attached form are being called to the attention of the Examiner. In accordance with 37 CFR §1.98(d), copies of the references on the attached form filed 05/21/03 can be found in US Application No. **09/823,712**, filed 03/30/01 (Attorney Docket No. 001803-326-999). This application is a continuation of US Application No. **09/823,712**. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and

no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement, since it is being submitted prior to the first Office Action. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



Matthew E. Hinsch  
Reg. No. 47,651

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Express Mail No. EL 451 600 282 US  
Date Mailed: May 21, 2003  
Serial Number: 09/823,712  
Filing Date: March 30, 2001  
Inventors: Sagner et al  
For: METHOD FOR DETERMINING THE EFFICIENCY OF NUCLEIC  
ACID AMPLIFICATIONS

***Enclosures:***

- 1) Information Disclosure Statement (in duplicate)
- 2) List of References Cited by Applicant
- 3) Copies of References A01-A16 (1 binder)

File No. 001803-326-999

Sender: NCG/RRP/SYM/mo

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Sagner *et al*

Confirmation No.: 7485

Serial No.: 09/823,712

Group Art Unit: 1634

Filed: March 30, 2001

Examiner: Chakrabarti, A

For: METHOD FOR DETERMINING THE  
EFFICIENCY OF NUCLEIC ACID  
AMPLIFICATIONS

Attorney Docket No.: 5443  
(1803-326-999)

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

1. Enclosures accompanying this Information Disclosure Statement are:
  - 1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.
  - 1b. A legible copy of :
    - ☒ Each U.S. patent application publication and U.S. and foreign patent;
    - ☐ Each publication or that portion which caused it to be listed on the PTO-1449;
    - ☐ For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion;
    - ☐ all other information or portion which caused it to be listed on the PTO-1449.
  - 1c. ☒ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.
  - 1d. ☐ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications.
2. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):
  - ☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);

- ☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
- ☐ Before the mailing of the first Office action on the merits;
- ☐ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
3. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.

*(Check either Item 3a or 3b)*

- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
- 3b. ☒ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
- ☐ enclosed
- ☒ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

*(Item 3b to be checked if any reference known for more than 3 months)*

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:

- ☐ enclosed.
- ☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

The Certification Statement in Item 5 below is applicable.

5. ☐ Certification Statement (applicable if Item 3a or Item 4 is checked)

*(Check either Item 5a or 5b)*


- 5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- 5b. ☐ In accordance with 37 C.F.R. §1.97(e)(2), it is certified that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was known by any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
6. ☐ This application is a continuation application under 37 C.F.R. §1.60 or §1.53(b) or (d).

*(Check appropriate Items 6a, 6b and/or 6c)*

- 6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.
- 6b. ☐ Copies of publications listed on Form PTO-1449 from prior application Serial No. , filed on , of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).
- 6c. ☐ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application Serial No. , filed on , and are provided herewith.
7. ☐ This is a Supplemental Information Disclosure Statement. (Check either Item 7a or 7b)
- 7a. ☐ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on . A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on .
8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:
- ( Check Item 8a, 8b, or 8c)
- 8a. ☐ satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.
- 8b. ☐ set forth in the application.
- 8c. ☐ enclosed as an attachment hereto.
9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Pennie & Edmonds LLP Deposit Account No. 16-1150.
10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

Date: May 21, 2003

  
Rahul Pathak

42,983  
(Reg. No.)

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LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)	ATTY DOCKET NO. 1803-326-999	APPLICATION NO 09/823,712
	APPLICANT Sagner <i>et al.</i>	
	FILING DATE March 30, 2001	GROUP 1631

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A01	US 2,516,655	7/25/1950	Smith, T.R.			
	A02	US 3,163,404	12/29/1964	Kraft <i>et al.</i>			
	A03	US 3,614,434	10/19/1971	Horwitz			
	A04	US 3,711,379	1/16/1973	Adams			
	A05	US 5,499,872	3/19/1996	Baxter			
	A06	US 5,580,524	12/03/1996	Forrest <i>et al.</i>			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	A07	EP 0 640 828 A1	8/16/94	EP				
	A08	EP 0 959 140 A2	6/04/99	EP				
	A09	WO 99/54510	10/28/99	PCT				
	A10	EP International Search Report EP 01 10 7737	2/14/03	EP				
	A11	EP International Search Report Corresponding to EP 01 10 7738	3/17/03	EP				

## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	A12	Bourinbaiair <i>et al.</i> , "Simple Procedure For Estimating The Efficiency of PCR," Molecular Biotechnology (1996) 6:87-90
	A13	Fujii <i>et al.</i> , "Mutation Detection by TaqMan-Allele Specific Amplification: Application to Molecular Diagnosis of Glycogen Storage Disease Type Ia and Medium Chain Acyl-CoA Dehydrogenase Deficiency," Human Mutation (2000) 15:189-196
	A14	Isono K. "A Novel Quantitative PCR With Fluorogenic Probe," The Japanese Journal of Clinical Pathology, (1997) 45 218-223 *Abstract
	A15	LightCycler System. Roche Molecular Biochemicals (1999) 1-6.
	A16	Rodriguez-Antona <i>et al.</i> , "Quantitative RT-PCR Measurement of Human Cytochrome P-450s: Application to Drug Induction Studies," (2000) Archives of Biochemistry and Biophysics 376:109-116

EXAMINER	DATE CONSIDERED
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	